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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/571,802 12/13/95 ISHII

EXAMINER

HM11/0501

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ART UNIT	PAPER NUMBER
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DATE MAILED:

05/01/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4-16-98 (Paper NO. 12)

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 3-6, 10-13, 24-45 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 3-6, 10-13, 24-45 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Detailed Action

Continued Prosecution Application

1. Receipt is acknowledged of the "conditional" request on 17 February 1998 for a Continued Prosecution Application (CPA) filed under 37 CFR 1.53(d) based on prior Application No. 08/571,802. Any "conditional" request for a CPA submitted as a separate paper is treated as an unconditional request for a CPA. Accordingly, the request for a CPA application is acceptable and a CPA has been established. An action on the CPA follows.

2. The preliminary amendments filed 22 December 1995 (paper No. 9) and filed 16 April 1998 (paper No. 12) have been entered.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office actions.

Claim Objections

4. Claims 3-6 and 10-13 are objected to because of the following informalities:

Claims 3-6 and 10-13 are dependent on cancelled claims. Appropriate correction is required.

Information Disclosure Statement

The list of references labeled A1-A6 in the IDS filed 16 April 1998 (paper No. 12) has been changed to D1-D6, respectively, because the same labeling A1-A6 has been used previously in the IDS filed 4 April 1996 (Paper No.4).

Claim Rejections - 35 USC § 112

5. Claims 3-6, 10-13, and 24-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of parenteral administration of IGF-I, IGF-II, or a combination of both IGF-I and II for the treatment of locus ceruleus noradrenergic neurons ablation by 6-hydroxydopamine, does not reasonably provide the full scope of enablement for parenteral administration of IGF-I or IGF-II, for traumatic injury of the central nervous system (CNS) or spinal cord and treating stroke. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons set forth in the past office actions.

The terms "traumatic injury to the central nervous system" encompass a physical or mental injury to the central nervous system (see Stedman's Medical Dictionary(U)). Thus, claims 24-33 encompass any physical or mental injury to the CNS. However, as

discussed in the past office actions, the specification does not enable the full scope of the claimed invention.

The terms "traumatic brain injury" encompass a physical or mental injury to the brain(see Stedman's Medical Dictionary(U)). Thus, claims 40-45 encompass any physical or mental injury to the brain. However, as discussed in the past office actions, the specification does not enable the full scope of the claimed invention.

The term "stroke" encompass both ischemic or hemorrhagic legions. Thus, claims 34-45 encompass treament for all types of stroke. However, the specification fails to teach the treatment for the full scope of stroke diseases. The state of the art is silent with respect to using IGF to treat stroke (see Berkow et al.(V)). The treatments are related to using anticoagulants or treating atherosclerosis or hypertension, but not using IGF. Furthermore, the specification fails to make a nexus from the model of using IGF-I and II for the treatment of locus ceruleus noradrenergic neurons ablation by 6-hydroxydopamine to treating stroke. Without such guidance, the determination of IGF-I or -II effect on treating the full scope of stroke diseases requires empirical experimentation. Thus without further guidance, it would require undue experimentation to stroke by administering IGF- or IGF-II.

Applicant argues that the post-filing date evidnece clearly

demonstrates the operativeness of the methods in a mammal as taught and claimed. However, applicant has failed to make a nexus from the model in the specification of using IGF-I and II for the treatment of locus ceruleus noradrenergic neurons ablation by 6-hydroxydopamine to treating stroke, traumatic injury to the CNS or the brain. Furthermore, the specification fails to teach the methods of administration of IGF which results in treating a model or the diseases of stroke or traumatic injury to the brain or CNS.

Claim Rejections - 35 USC § 102

6. Claims 3-6, 10-13, and 24-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (A1) for the reasons set forth in the past office actions (Paper Nos. 5 and 8) and set forth below.

The terms "traumatic injury to the central nervous system" or "traumatic brain injury" encompass a physical or mental injury to the central nervous system or brain. Lewis et al. teach the method of treating injury and stroke (column 4, lines 1-22).

Applicant argues that Lewis et al. does not teach IGF acting across the blood-brain barrier but rather teach away by characterizing the blood brain barrier as a problem. However, Lewis et al. teach the method of parenteral administration of IGF-I or IGF-II with specific dosage ranges of 1ug/kg/day to 1

g/kg/day as well as ranges 0.01 mg/kg/day to 100mg/kg/day (column 10, lines 3-22). Furthermore, IGF I and II inherently cross the blood brain barrier. Thus, the prophetic contemplation of potential problems does not exclude the teachings of Lewis et al.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cephalon, Inc.(B2) is a cumulative reference with Lewis et al.(A1).

Stedman's Medical Dictionary (U) teaches that the definition of "trauma" is an injury, physical or mental.

Reinhadt et al.(A58) teach that IGF I and II cross the blood brain barrier inherently.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MDP
Michael D. Pak
1812
24 April 1998

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800